

1 METHODS AND APPARATUS FOR SCLEROSING THE WALL OF A VARICOSE VEIN

2
3 This application claims the benefit of the following
4 provisional applications: serial number 60/219,931 filed July 21,
5 2000; serial number 60/221,469 filed July 26, 2000; serial number
6 60/225,172 filed August 14, 2000 the complete disclosures of which
7 are hereby incorporated herein by reference.
8

9 BACKGROUND OF THE INVENTION

10
11 1. Field of the Invention

12 The invention relates to the treatment and correction of
13 venous insufficiency or varicose veins. More particularly the
14 invention relates to a minimally invasive procedure using a
15 catheter-based system to sclerose the wall of the vein.
16

17 2. State of the Art

18 The human venous system of the lower limbs consists
19 essentially of the superficial venous system and the deep venous
20 system with perforating veins connecting the two systems. The
21 superficial system includes the long or great saphenous vein and
22 the short saphenous vein. The deep venous system includes the
23 anterior and posterior tibial veins which unite to form the
24 popliteal vein, which in turn becomes the femoral vein when joined
25 by the short saphenous vein.

1
2 The venous systems contain numerous one-way valves for
3 directing blood flow back to the heart. Venous valves are usually
4 bicuspid valves, with each cusp forming a sack or reservoir for
5 blood which, under pressure, forces the free surfaces of the cusps
6 together to prevent retrograde flow of the blood and allow
7 antegrade flow to the heart. An incompetent valve is a valve
8 which is unable to close because the cusps do not form a proper
9 seal and retrograde flow of blood cannot be stopped.

10
11 Incompetence in the venous system can result from vein
12 dilation. Separation of the cusps of the venous valve at the
13 commissure may occur as a result. Two venous diseases which often
14 involve vein dilation are varicose veins and chronic venous
15 insufficiency.

16
17 The varicose vein condition includes dilatation and
18 tortuosity of the superficial veins of the lower limb, resulting
19 in unsightly discoloration, pain and ulceration. Varicose veins
20 often involve incompetence of one or more venous valves, which
21 allow reflux of blood from the deep venous system to the
22 superficial venous system or reflux within the superficial system.

23
24 Varicose veins are compatible with long life and rarely cause
25 fatal complications, but the condition significantly decreases the

1 quality of life. Patients complain primarily of leg fatigue,
2 dull, aching pains, ankle swelling, and ulcerations.
3 Occasionally, thrombosis occurs in dilated subcutaneous channels,
4 resulting in local pain, induration, edema, inflammation, and
5 disability. In addition to those problems, the high visibility of
6 the unattractive rope-like swellings and reddish skin blotches
7 causes considerable distress for both men and women. Lastly,
8 varicose eczema, which is a local reddened swollen and itching
9 skin condition can occur and can spread to distant parts of the
10 body (called an "Id reaction").

11
12 Phleboscclerosis, the destruction of venous channels by the
13 injection of sclerosing agents, has been used to treat varicose
14 veins since 1853, when Cassaignae and Ebout used ferric chloride.
15 Sodium salicylate, quinine, urea, and sodium chloride have also
16 been used, but the agent more recently favored is sodium
17 tetradecyl sulfate. In order for phleboscclerosis to be effective,
18 it is necessary to evenly dispense the sclerosing agent throughout
19 the wall of the vein without using toxic levels of the sclerosing
20 agent. This is not particularly difficult for the smaller veins.
21 However, it is quite difficult or nearly impossible in larger
22 veins. When a larger vein is injected with a sclerosing agent,
23 the sclerosing agent is quickly diluted by the substantially
24 larger volume of blood which is not present in smaller veins. The
25 result is that the vein is sclerosed (injured) only in the

1 vicinity of the injection. If the procedure is continued, and the
2 injections are far apart, the vein often assumes a configuration
3 resembling sausage links. The problem cannot be cured by
4 injecting a more potent solution of sclerosing agent, because the
5 sclerosing agent may become toxic at such a concentration.

6
7 U.S. Patent Number 5,676,962 discloses an injectable
8 microfoam containing a sclerosing agent. The microfoam is
9 injected into a vein where it expands and, theoretically, achieves
10 the same results as a larger quantity of sclerosing agent without
11 the toxicity. Such a foam is presently manufactured under the
12 trademark Varisolve® by Provensis, Ltd., London, England. Recent
13 clinical trials of the foam indicate a success rate of 81%.

14
15 Until recently, the preferred procedure for treating the
16 great saphenous vein was surgical stripping. This highly invasive
17 procedure involves making a 2.5 cm incision in the groin to expose
18 the saphenofemoral junction, where the great saphenous vein and
19 its branches are doubly ligated en masse with a heavy ligature.
20 The distal portion of the vein is exposed through a 1 cm incision
21 anterior to the medial malleolus, and a flat metal or plastic
22 stripper is introduced to exit in the proximal saphenous vein.
23 The leg is held vertically for 30 seconds to empty the venous tree
24 before stripping the vein from the ankle to the groin. If the
25 small saphenous vein is also incompetent, it is stripped at the

1 same time from an incision posterior to the lateral malleolus to
2 the popliteal space. After stripping the veins, the leg is held
3 in the vertical position for three to four minutes to permit
4 vessel ends to retract, constrict, and clot.

5
6 After the stripping procedure, collateral veins are removed
7 by the avulsion-extraction technique which is illustrated
8 schematically in prior art Figure 1. By working through small (5
9 to 8 mm) transverse incisions, segments of vein 10 to 20 cm long
10 can be removed by dissecting subcutaneously along the vein with a
11 hemostat, and then grasping, avulsing, and removing the vein.
12 With practice, long segments of vein in all quadrants can be
13 removed through these small incisions. No attempt is made to
14 ligate the branches or ends of the veins, since stripping has
15 shown it to be unnecessary. Bleeding is controlled by elevation
16 and pressure for two to four minutes. As many as 40 incisions are
17 made in severe cases, but their small size and transverse
18 direction permit closure with a single suture.

19
20 Before closure of the incisions, a rolled towel is rolled
21 repeatedly from the knee to the ankle and from the knee to the
22 groin to express any clots that may have accumulated. The groin
23 incision is approximated with three 5-0 nylon mattress sutures and
24 all other incisions are closed with a single suture.

1 As can be readily appreciated, the stripping and avulsion-
2 extraction procedures are relatively invasive and require
3 significant anaesthesia. It can therefore be appreciated that it
4 would be desirable to provide an alternative, less invasive
5 procedure which would accomplish the same results as stripping and
6 avulsion-extraction.

7
8 Recently, a number of patents have issued disclosing the
9 treatment of varicose veins with RF energy. Illustrative of these
10 recent patents are: U.S. Patent #6,200,312 entitled "Expandable
11 Vein Ligator Catheter Having Multiple Electrode Leads"; U.S.
12 Patent #6,179,832 entitled "Expandable Catheter Having Two Sets of
13 Electrodes"; U.S. Patent #6,165,172 entitled "Expandable Vein
14 Ligator Catheter and Method of Use"; U.S. Patent #6,152,899
15 entitled "Expandable Catheter Having Improved Electrode Design,
16 and Method for Applying Energy"; U.S. Patent #6,071,277 entitled
17 "Method and Apparatus for Reducing the Size of a Hollow Anatomical
18 Structure"; U.S. Patent #6,036,687 entitled "Method and Apparatus
19 for Treating Venous Insufficiency"; U.S. Patent #6,033,398
20 entitled "Method and Apparatus for Treating Venous Insufficiency
21 Using Directionally Applied Energy"; U.S. Patent #6,014,589
22 entitled "Catheter Having Expandable Electrodes and Adjustable
23 Stent"; U.S. Patent #5,810,847 entitled "Method and Apparatus for
24 Minimally Invasive Treatment of Chronic Venous Insufficiency";
25 U.S. Patent #5,730,136 entitled "Venous Pump Efficiency Test

1 System And Method"; and U.S. Patent #5,609,598 entitled "Method
2 and Apparatus for Minimally Invasive Treatment of Chronic Venous
3 Insufficiency". These patents generally disclose a catheter
4 having an electrode tip which is switchably coupled to a source of
5 RF energy. The catheter is positioned within the vein to be
6 treated, and the electrodes on the catheter are moved toward one
7 side of the vein. RF energy is applied to cause localized heating
8 and corresponding shrinkage of the adjacent venous tissue. After
9 treating one section of the vein, the catheter can be repositioned
10 to place the electrodes to treat different sections of the vein.

11
12 Although this procedure has gained acceptance and is less
13 invasive than the stripping and avulsion-extraction procedures,
14 there are several disadvantages to it. In particular, RF
15 treatment is actually quite slow and painful and the patient must
16 be sufficiently anaesthetized along the entire length of the veins
17 to be treated. In addition, repositioning the catheter is time
18 consuming thus requiring anaesthesia for a prolonged period.
19 Moreover, the RF treatment is incomplete, as only a portion of the
20 vein wall is actually treated, i.e. the portion contacting the
21 electrode. The partially treated vein may eventually re-
22 cannularize. Furthermore, tributary veins remain unaffected and
23 must be treated separately.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide methods and apparatus for the minimally invasive treatment of varicose veins.

It is also an object of the invention to provide methods and apparatus for the minimally invasive treatment of varicose veins wherein only minimal anaesthesia is required.

It is another object of the invention to provide methods and apparatus for the minimally invasive treatment of varicose veins wherein tributary veins are treated simultaneously with the vein to which they connect.

It is an additional object of the invention to provide methods and apparatus for the minimally invasive treatment of varicose veins and connecting tributaries wherein the entire wall of the vein is evenly sclerosed.

Another object of the invention is to provide methods and apparatus for the minimally invasive treatment of varicose veins which do not utilize high concentration sclerosing agents.

1 In accord with these objects which will be discussed in
2 detail below, a first embodiment of the present invention includes
3 a catheter having three concentric tubes: an innermost tube, an
4 outer tube, and an intermediate tube. The innermost tube has two
5 lumena: a guide wire lumen and an inflation lumen. The distal end
6 of the innermost tube has an atraumatic tip and an integral
7 inflatable occlusion balloon in fluid communication with the
8 inflation lumen. The intermediate tube has a single lumen through
9 which the innermost tube extends. The distal end of the
10 intermediate tube has a self-expanding balloon with a plurality of
11 fluid pores in fluid communication with the lumen of the
12 intermediate tube. The outer tube has a single lumen through
13 which the intermediate tube extends. The proximal ends of the
14 innermost and intermediate tubes are provided with fluid fittings.
15 The proximal ends of the outer tube and the intermediate tube are
16 provided with sealing fittings.

18 An exemplary treatment method using the first embodiment of
19 the invention includes elevating the foot above the groin,
20 delivering the catheter via a guide wire into the saphenous vein
21 from the ankle to the groin. The patient is then placed in a
22 Trendelenberg position (the body inclined downward approximately
23 30 degrees and the leg elevated approximately 60 degrees. The
24 inflatable occlusion balloon is inflated sufficiently to block
25 blood flow, and moving the outer tube relative to the intermediate

1 tube (or vice versa) such that the self-expanding balloon expands
2 and contacts the wall of the vein. With the inflatable occlusion
3 balloon securely in place, the intermediate and outer tubes are
4 pulled away from the inflatable occlusion balloon while sclerosing
5 agent is injected into the lumen of the intermediate tube. The
6 sclerosing agent exits the self-expanding balloon through its
7 pores and directly contacts the wall of the vein. Pressure
8 exerted by the self-expanding balloon both massages the wall of
9 the vein and squeegees sclerosing agent evenly into the vein wall.
10 Collateral tributary veins are injected with sclerosing agent as
11 the self-expanding balloon passes over them. The diameter of the
12 self-expanding balloon becomes progressively smaller as it is
13 moved from the groin area toward the ankle because the diameter of
14 the vein changes accordingly. When the entire vein has been
15 sclerosed, the inflatable occlusion balloon is deflated and the
16 catheter is removed and the incision is sealed. The leg is
17 preferably wrapped with a compression bandage for a few days
18 during which the veins flatten out, thereby removing blood from
19 the vein and allowing the walls of the vein to fuse to itself.

20
21 According to the exemplary treatment using the first
22 embodiment of the catheter, only one small incision is made in the
23 ankle and only a small amount of anesthetic is required at the
24 place of the incision. The procedure is relatively painless.
25 Tributary veins are treated simultaneously with the vein into

1 which they feed. The entire wall of the vein is evenly sclerosed.
2 Because blood flow is blocked and sclerosing agent is applied
3 directly to the wall of the vein, a lower concentration of
4 sclerosing agent can be used as it is not diluted by flowing
5 blood. The occlusion balloon also prevents sclerosing agent from
6 exiting the treated vein and entering into another vein.

7
8 According to an alternative embodiment, sclerosing agent may
9 be injected through the lumen of the outer tube. In either case,
10 the self-expanding balloon causes the sclerosing agent to be
11 evenly distributed and massaged into the wall of the vein.

12
13 A second embodiment of the catheter of the invention has four
14 tubes, two of which are equipped with inflatable occluding
15 balloons. The procedure for using this embodiment involves
16 inflating one balloon upstream and the other downstream and moving
17 the self-expanding balloon between them. The two balloons can be
18 inflated to isolate a tributary for sclerosing.

19
20 A third embodiment has only one balloon which massages the
21 wall of the vein as sclerosing agent is injected downstream of the
22 balloon.

1 A fourth embodiment utilizes a brush having hollow bristles
2 to massage the wall of the vein as sclerosing agent is injected
3 through the bristles.

4
5 According to the presently preferred embodiments, a drug
6 dispenser attachment is provided to automatically inject the
7 sclerosing agent as the self-expanding balloon is moved through
8 the vein. The drug dispenser, which may or may not be disposable,
9 attaches to a disposable syringe and includes a rack and pinion
10 gear system for engaging the plunger of the syringe. The gear
11 system is driven by a spool carrying a filament, a ribbon, or a
12 cable. The drug dispenser is attached to the patient's leg with
13 straps and the end of the cable is attached to the intermediate
14 tube of the catheter such that as the self-expanding balloon is
15 moved through the vein, the cable is pulled causing the spool to
16 rotate and the rack and pinion gears to engage the plunger of the
17 syringe and dispense the sclerosing agent. Alternatively, the
18 dispenser may be attached to the catheter and the cable attached
19 to the patient's leg.

20
21 In addition to treating varicose veins, the methods and
22 apparatus can be used for the delivery of other intravascular
23 medications such as antiproliferative drugs, for example,
24 Paclitaxel or Rapamycin to coronary arteries and the like, to
25 prevent restenosis of these vessels after stenting. The device

1 can also be used to deliver drugs to other hollow tubes such as
2 the fallopian tubes or to persistent abnormal sinus tracts.

3
4 Additional objects and advantages of the invention will
5 become apparent to those skilled in the art upon reference to the
6 detailed description taken in conjunction with the provided
7 figures.

8
9 BRIEF DESCRIPTION OF THE DRAWINGS

10
11 Figure 1 is a schematic illustration of a prior art technique
12 for the treatment of varicose veins;

13
14 Figure 2 is a broken side elevation in partial section
15 illustrating a first embodiment of a catheter according to the
16 invention;

17
18 Figure 3 is a sectional view taken along line A-A of Figure
19 2;

20
21 Figure 4 is a view similar to Figure 2 but illustrating the
22 inflatable occlusion balloon inflated inside a vein;

23
24 Figure 5 is a view similar to Figure 4 but illustrating the
25 self-expanding balloon expanded inside a vein;

1

2 Figure 6 is a view similar to Figure 5 but illustrating the
3 self-expanding balloon after having traversed a portion of the
4 vein;

5

6 Figure 7 is a view similar to Figure 6 but illustrating a
7 second embodiment of the catheter of the invention;

8

9 Figure 8 is a view similar to Figure 7 but illustrating a
10 third embodiment of the invention;

11

12 Figure 8a is a view similar to Figure 8 but illustrating a
13 fourth embodiment of the invention;

14

15 Figure 8b is an enlarged schematic distal end view of the
16 embodiment of Figure 8a;

17

18 Figure 9 is a perspective view of a drug dispenser according
19 to the invention;

20

21 Figure 10 is a partially cut away top view of the drug
22 dispenser of Figure 9; and

23

24 Figure 11 is an enlarged perspective view of a winding clutch
25 of the drug dispenser.

1
2 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS
3

4 Referring now to Figures 2 and 3, a first embodiment of the
5 present invention includes a catheter 10 having three concentric
6 tubes: an innermost tube 12, an outer tube 14, and an
7 intermediate tube 16. The innermost tube 12 has two lumens: a
8 guide wire lumen 18 and an inflation lumen 20. The distal end of
9 the innermost tube includes an atraumatic tip 22 and an integral
10 inflatable occlusion balloon 24 in fluid communication with the
11 inflation lumen 20. The intermediate tube 16 has a single lumen
12 26 through which the innermost tube extends. The distal end of
13 the intermediate tube 16 is provided with a self-expanding balloon
14 28 with a plurality of fluid pores 30 in fluid communication with
15 the lumen 26 of the intermediate tube. The outer tube 14 has a
16 single lumen 32 through which the intermediate tube 16 extends.
17

18 The proximal end of the innermost tube 12 has a guide wire
19 hub 34 which provides access to the guide wire lumen 18 and a
20 fluid port 36 in fluid communication with the inflation lumen 20.
21 The proximal end of the intermediate tube 16 is provided with a
22 fluid port 38 in fluid communication with the lumen 26 and two
23 fittings 40, 42. The fitting 40 allows the innermost tube 12 and
24 intermediate tube 16 to be moved relative to each other while
25 maintaining a seal of the annular fluid space between the

1 innermost tube 12 and intermediate tube 16. It will be
2 appreciated that the proximal end of the tube 16 can be reinforced
3 with metal tubing such as thin-walled hypodermic tubing to make it
4 easier to push and provide a more uniform sealing surface. The
5 fitting 42 is either press fit or glued to the proximal end of the
6 intermediate tube 16 or attaches to a luer hub which is press fit
7 or glued to the proximal end of the intermediate tube 16. The
8 proximal end of the outer tube 14 has a fitting 44 that seals the
9 space between the outer tube 14 and the intermediate tube 16 and
10 also releasably locks their relative positions.

11
12 An exemplary treatment method using the first embodiment of
13 the invention can be understood with reference to Figures 4-6.
14 After anesthetizing the patient's ankle, a guide wire (not shown)
15 is fed into the saphenous vein V from the ankle to the groin of
16 the patient. The guide wire can be fed from a cut-down to the
17 vein at the ankle or by using percutaneous entry techniques well
18 known in the art which generally involves the use of a catheter
19 sheath introducer, and the like. Once the guide wire is in place,
20 the catheter assembly 10 is threaded over the guide wire and
21 follows the guide wire up the leg such that the tip 22 of the
22 occlusion balloon 24 is located in a desired location, e.g., just
23 proximal to the exit of the saphenous vein in the vicinity of the
24 profunda vein. The exact location of the occlusion balloon can be
25 identified by ultrasound, palpation, or by angiography, and the

1 like. The occlusion balloon 24 is then inflated with a gas or
2 fluid through the port 36. CO₂ gas is the preferred inflator
3 because it is easy to see with ultrasound and it is safely
4 absorbed into the blood stream should any leakage occur. Once the
5 occlusion balloon 24 is inflated, blood can no longer pass to or
6 from the saphenous vein V via the profunda vein (not shown).
7

8 With the inflated occlusion balloon in place, as is shown in
9 Figures 4 and 5, the fitting 44 of the outermost tube 14 is
10 loosened and the tube 14 is slid backwards over intermediate tube
11 16 such that the fitting 44 butts up against connector fitting 42
12 as shown in Figure 5. Retracting the outer tube 14 in this manner
13 releases self-expanding balloon 28, which self-expands until it
14 hits the wall of the varicose vein V.
15

16 According to the presently preferred embodiment, the self-
17 expanding balloon 28 is made of a braided mesh, which is braided
18 such that its preferred stable state is fully expanded. The wires
19 of the mesh are of a spring material such as stainless steel,
20 cobalt-chrome-nickel (Elgiloy wire), nitinol or the like.
21 Alternatively, the self-expanding balloon wires may be made of a
22 plastic such as PET, PMMA, polyurethane, nylon or the like. The
23 wires may or may not be heat hardened to impart greater spring-
24 like properties and memory to the mesh. Filling the spaces
25 between the braid wires is a thin membrane 49 made from an

1 elastomeric material such as polyurethane, silicone rubber,
2 polyolefin, polyamide copolymers and the like. The membrane can
3 be formed by dip molding, insert molding or it can be formed
4 separately and glued in place. Those skilled in the art will
5 appreciate that the self-expanding balloon both shortens in length
6 and widens in diameter as it achieves its preferred expanded
7 state. It will be appreciated that the distal end of the balloon
8 28 is dimensioned such that it can move over the inner tube 12 but
9 still maintain a fluid seal between the balloon 28 and the tube
10 12. As illustrated in Figures 4-6, a plurality of fluid pores 30
11 in the membrane 49 are located about the circumference of the
12 balloon 28.

13
14 When the catheter 10 is in the position shown in Figure 5, a
15 source of sclerosing agent (or a microfoam containing a sclerosing
16 agent) is coupled to the port 38 and operated to allow sclerosing
17 agent to flow through the annular space between the tubes 12 and
18 16, into the balloon 28 and out through the pores 30. It will be
19 appreciated that sclerosing agent so dispensed with flow directly
20 into the wall of the vein V. According to the invention, as
21 sclerosing agent is being dispensed, the self-expanding balloon 28
22 is moved away from the balloon 24 as shown in Figure 6 by moving
23 the tubes 14 and 16 relative to the tube 12. It will be
24 appreciated that as the balloon 28 is moved along the length of
25 the tapering vein V, the balloon decreases in diameter and

1 lengthens. The sclerosing agent exiting the pores 30 is massaged
2 or "squeegeed" into the wall of the vein V by means of the outward
3 pressure exerted by the balloon 28 against the wall of the
4 vessel V.

5
6 Figure 6 shows the occlusion balloon 24 remaining in place as
7 the self-expanding balloon 28 has traversed along a length of the
8 vessel V. Sclerosing agent is continually injected through the
9 balloon 28 as it is withdrawn. It can also be appreciated that as
10 the balloon 28 passes collateral (tributary) veins such as those
11 identified as T1 and T2, sclerosing agent fills the collateral
12 veins to effectively cause them to sclerose. It will be
13 appreciated that additional sclerosing agent can be injected into
14 the tributary veins by means of a second syringe fluidly coupled
15 to the inlet port 38 by means of a T-connector

16
17 According to the presently preferred embodiment, the balloon
18 28 is withdrawn through the entire length of the vein V to be
19 sclerosed. When the entire length is traversed, the occlusion
20 balloon 24 is deflated, the catheter 10 is removed and the
21 puncture site is sealed. Simultaneous with the removal of the
22 occlusion balloon, or just prior to deflation of the balloon, or
23 even during the procedure, the leg of the patient is preferably
24 wrapped with an elastic compression bandage, e.g, an ACE BANDAGE,
25 with other compression objects such as foam, etc.. Wrapping the

1 leg in this manner causes the vein to flatten-out, thereby
2 removing blood from the vein and allowing the lumen to fuse to
3 itself in the collapsed embodiment. After a few days of
4 compression the bandages are removed and the vein is no longer
5 medically or cosmetically problematic.

6
7 It has been discovered that, due to the "squeegee-like"
8 action of the self-expanding balloon 28, the sclerosing agent need
9 not be dispensed at the outer circumference of the balloon. Thus,
10 the pores 30 of the balloon may be located on the proximal portion
11 of the balloon. Alternatively, the balloon need not have any
12 pores, but pores may be provided at the distal end of the tube 16.
13 As yet another alternative, neither the balloon nor the
14 intermediate tube are provided with pores, but the sclerosing
15 agent is provided via the outer tube 14. In all cases, the
16 sclerosing agent will flow or be forced toward the wall of the
17 vein and be massaged into the vein wall by the balloon 28.

18
19 Those skilled in the art will appreciate that if the
20 sclerosing agent is not injected through the balloon 28, the
21 balloon need not be self-expanding. It could be an inflatable
22 balloon which is inflated with a gas or a saline solution from an
23 IV bag, etc. In this embodiment, the pressure can be adjusted as
24 the balloon traverses the vein and the diameter of the vein
25 changes.

1
2 As mentioned above, the catheter of the invention can be used
3 to deliver other types of intravascular medication directly to the
4 wall of a vein. Although the treatment of varicose veins
5 generally involves treating the entire length of the vein, other
6 treatments may require or prefer that only a selected portion of
7 the blood vessel be treated. Accordingly, a second embodiment of
8 the invention is illustrated in Figure 7 in which two inflatable
9 occlusion balloons are provided to isolate a region of a blood
10 vessel for treatment.

11
12 As shown in Figure 7, the catheter 110 has four tubes: an
13 innermost tube 112, an outer tube 114, and two intermediate tubes
14 116 and 117. The innermost tube 112 has an inflatable balloon 124
15 with an atraumatic tip 122 at its distal end. The innermost tube
16 112 is substantially the same as the tube 12 described above. The
17 outer tube 114 and intermediate tube 116 are also substantially
18 the same as the tubes 14 and 16 described above. The additional
19 tube 117 resides in the annular space between the tubes 114 and
20 116. It has an inflatable balloon 125 at its distal end and is
21 similar to the tube 112 in that it has two lumen, one of which
22 carries the tube 116 and the other of which is used to inflate the
23 balloon 125. The procedure for using this embodiment involves
24 inflating one balloon upstream and the other downstream and moving
25 the self-expanding balloon between them while injecting an

1 intravascular drug. This allows treatment of a selected portion
2 of a blood vessel without diluting the treatment drug. It will
3 also be appreciated that the catheter 110 can also be used to
4 isolate one or a plurality of tributary veins by inflating the
5 balloons on opposite sides of the tributary or tributaries.
6 Sclerosing agent is then injected between the balloons and forced
7 into the tributary or tributaries,

8
9 A third embodiment of a catheter 210 according to the
10 invention is shown in Figure 8. This embodiment includes an outer
11 tube 214 and an inner tube 216. The distal end of the inner tube
12 216 is provided with a self-expanding balloon 228. According to
13 this embodiment, the balloon 228 is optionally provided with an
14 abrasive surface 231 and/or pores (not shown). When an abrasive
15 surface is provided, the catheter 210 may be used with or without
16 a sclerosing agent. In these instances, treatment may consist of
17 abrading the wall of the blood vessel with the abrasive surface
18 231 of the balloon 228. In other instances, where pores are
19 provided in the balloon, treatment may consist of abrading the
20 wall of the vein (if the balloon has an abrasive surface) as the
21 sclerosing agent is injected out of the pores. In yet other
22 instances, when no pores are provided in the balloon, treatment
23 may include injecting an intravascular drug through the annular
24 space between the outer tube 214 and the inner tube 216 or through
25 pores (not shown) at the distal end of the inner tube 216. If the

1 balloon 228 is moved against the flow of the drug (from right to
2 left as seen in Figure 8), the drug will be massaged into the wall
3 of the blood vessel (which is abraded if the balloon has an
4 abrasive surface) by the balloon 228.

5
6 A fourth embodiment of a catheter 410 according to the
7 invention is shown in Figures 8a and 8b. This embodiment includes
8 an outer tube 414 and an inner tube 416. The distal end of the
9 inner tube 416 is provided with a brush 430 having a plurality of
10 hollow bristles, e.g. 430a-430p and a plug 418. The hollow
11 bristles are in fluid communication with the inner tube 416 such
12 that a sclerosing agent may be injected through the tube 416 and
13 exit the ends of the bristles. The bristles 430a-430p are
14 preferably made of a resilient material so that they will expand
15 to the position shown in the Figures, i.e., approximately radial
16 to the inner tube, when released from the outer tube. A method
17 for using the fourth embodiment includes moving the outer tube
18 and/or inner tube until the bristles 430a-430p are collapsed
19 inside the outer tube, delivering the two tubes to a procedural
20 site in a blood vessel, moving the outer tube and/or inner tube
21 until the bristles 430a-430p are expanded as shown in the figures,
22 then moving the inner tube relative to the blood vessel while
23 injecting a sclerosing agent through the inner tube and the
24 bristles.

25

1 According to the presently preferred embodiments, a drug
2 dispenser attachment is provided to automatically inject the
3 sclerosing agent as the self-expanding balloon is moved through
4 the vein. Figure 9 shows a three dimensional view of a drug
5 dispenser 300 with a body 302 defining a channel for receiving a
6 disposable syringe 304, an injector cam 306, a string 308 with a
7 hook 309, a winding clutch 310 (shown in further detail in Figure
8 11) and slots 312.

9
10 Figure 10 is a partially cut away top view of the dispenser
11 300. As shown in Figure 10, the string 308 with hook 309 is wound
12 on spool 314. The spool 314 is rigidly attached to the winding
13 clutch 310 and clutchingly attached to an axle 316. The axle 316
14 is rigidly attached to a spur gear 318. The spur gear 318 engages
15 a second spur gear 320, which in turn is rigidly attached to an
16 axle 322 which carries a pinion gear 324. The pinion gear 324
17 engages a rack 326, which is attached to the injector cam 306. As
18 seen in Figure 10, the injector cam 306 is aligned with the
19 plunger 305 of the disposable syringe 304.

20
21 As seen in Figure 11, the winding clutch 310 includes a
22 clutch housing 328 and a cam 330. The clutch housing 328 defines
23 a center hole 332 through which the axle (316 in Figure 10)
24 extends. The cam 330 defines a hole 334 with an adjacent keyway
25 336. The cam 330 is spring biased by a spring 338 so that the

1 keyway 336 aligns with the hole 332 and engages flats (not shown)
2 which are machined on the axle (316 in Figure 10). When the cam
3 330 is pressed at 340, the hole 334 lines up with the hole 332 and
4 the flats on the axle are no longer engaged causing clutch 310 to
5 rotate without engaging the axle and without dispensing sclerosing
6 agent from syringe 304. This feature allows the string 305 to be
7 wound onto the spool 314. It also provides the surgeon with a
8 mechanism to lengthen or shorten the string without dispensing
9 sclerosing agent from the syringe.

10
11 The drug dispenser 300 works as follows. The body 302, with
12 the exit of the syringe 304 pointed towards the patient's foot, is
13 fastened to the patient's leg, preferably adjacent the ankle, via
14 straps such as VELCRO straps which are fed through the slots 312.
15 The sclerosing catheter (e.g. 10 in Figure 2) is maneuvered into
16 the patient's vein from a puncture site in the patient's ankle.
17 The proximal hub 42 (Fig. 2) of the sclerosing catheter is
18 attached to the hook 309 at the end of the string 308. As the
19 sclerosing catheter is pulled out of the vein, tension on string
20 308 causes pulley 314 to rotate which causes the pinion 324 to
21 rotate (via gears 318 and 320) and rack 326 to move. The cam 306
22 on the rack 326 presses the plunger 305 causing sclerosing agent
23 to be discharged from syringe 304. Those skilled in the art will
24 appreciate that a fluid conduit may be required to couple the
25 fluid exit of the syringe 304 to the fluid port 38 (Figures 2, 4,

1 and 5). It will also be appreciated that the gear ratios of the
2 drug dispenser can be selected such that the appropriate volume of
3 sclerosing agent dispenses as the catheter is pulled out of the
4 leg. The main purpose of the injector is to allow the physician
5 to dispense a continuous amount of sclerosing agent into the
6 patient as a function of the withdrawal of the catheter. It can be
7 appreciated that no sclerosing agent is discharged if the catheter
8 is not pulled and that the flow rate of sclerosing agent tracks
9 the speed at which the catheter is withdrawn. As mentioned above,
10 the drug dispenser can be used in conjunction with one of the
11 catheters to dispense other kinds of intravascular drugs for
12 different procedures.

13
14 Those skilled in the art will appreciate that the drug
15 dispenser may be attached to the catheter and the string attached
16 to the patient's leg. Moreover, it will be appreciated that the
17 clutch may be omitted if an adjustable length cable is used. It
18 will also be appreciated that other types of clutches could be
19 used at any of the gears or axles.

20
21 There have been described and illustrated herein several
22 embodiments of methods and apparatus for sclerosing the wall of a
23 varicose vein. While particular embodiments of the invention have
24 been described, it is not intended that the invention be limited
25 thereto, as it is intended that the invention be as broad in scope

1 as the art will allow and that the specification be read likewise.
2 For example, the catheter can be provided with an integral guide
3 wire and the catheter and the guide wire can be inserted
4 simultaneously. Also, the dual lumen catheter can be formed by
5 two concentric tubes with the inflation lumen being the annular
6 space between the tubes. It will therefore be appreciated by
7 those skilled in the art that yet other modifications could be
8 made to the provided invention, without deviating from its spirit
9 and scope as so claimed.

*Such as, the use of a foam or soft haired
brush to massage the sclerosing agent
into the wall of the vessel, and other
modifications,*

B.S.H. 6/29/01 R.P. 6/29/01

OR 6/29/01 JY 6/29/01